



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/551,546	04/18/00	NORIKAZU	T 087147/0437

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HM22/0627

EXAMINER

TRAVERS, R	
ART UNIT	PAPER NUMBER

1617
DATE MAILED: 06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/551,546

Applicant(s)
Tamura et al

Examiner
RUSSELL TRAVERS

Art Unit
1617



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20 and 22-36 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 20 and 22-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 20 and 28-33, drawn to a method for treating angiotensin II mediated diseases by administering an angiotensin II antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin converting enzyme inhibitory , or HMG-Co A inhibitory activity.

II. Claims 23 and 34-36, drawn to a method for treating various maladies by administering an angiotensin II antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin converting enzyme inhibitory , or HMG-Co A inhibitory activity.

III. Claims 22 and 24-26, drawn to a method for treating circulatory diseases by administering an angiotensin II antagonistic compound concomitantly with a compound possessing anti-hyperglycemic, angiotensin converting enzyme inhibitory , or HMG-Co A inhibitory activity.

Claims contained in Groups I, II and III are directed to methods for treating various diseases employing a plurality of patentably distinct species. Applicant is required under 35 U.S.C. § 121 to elect a single inventive group even though this requirement is traversed.

The presented inventions are only linked by the presented specification; with each invention requiring separate, distinct search, and consideration. The instant application was filed under 35 USC 371, requiring restriction by unity of invention. The

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authority for this restriction practice is found in 37 CFR 1.499. To restrict a case filed under 35 USC 371, the Examiner need not consider the burden posed by examining additional inventions; although such burden is present in the instant case.

Patent Cooperation Rules (PCT) Rules 13.1 and 13.2 permit in a single application only one invention. Thus, an application presenting more than one invention, as in the instant case, is appropriately restricted for lack of unity.

Groups I-III are directed to a plurality of distinct inventive species. Applicants must elect one of groups I-III for examination on the merits. Additionally, Applicant is required under 35 U.S.C. § 121 to elect an inventive species for examination on the merits, and present a claim directed to said single therapeutic treatment regimen and therapeutic compound mixture inventive species for examination on the merits. Said claim must be directed to a single disclosed inventive species: one disease, and one therapeutic mixture, residing under the penumbra of one of elected inventive groups I-III, even though this requirement is traversed.

As stated above, the presented inventions are only linked by the presented specification; with each invention requiring separate, distinct search, and consideration.

The above delineated inventions differ as distinct methods of therapy; are independent and patentably distinct each from the other. The grouped inventions differ as to their intended use, a reference which would anticipate the invention of one group would neither anticipate, nor make obvious the inventions in the other groups. The

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searches are not co-inclusive as indicated by the diverse nature of the subject matter. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

The grouped inventions are patentably distinct, a reference which would anticipate, or make obvious, any invention from groups I-III would not necessarily obviate, or anticipate, the inventions in any other group. The searches are not co-inclusive as indicated by the diverse nature of the subject matter, thus, would represent an undue burden on Examiner. One skilled in the art would readily practice the invention of one of the above groups with out infringing and or practicing the invention of another group. The subject matter is unique and has acquired a separate status in the art and is fully capable of supporting separate patents. For the foregoing reasons restriction is proper for examination purposes.

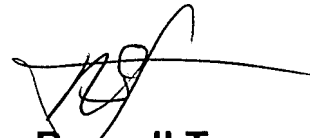
Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variations or clearly admit on the record that this is the case. In either instance, if Examiner finds one of the inventions unpatentable over

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the prior art, the evidence may be used in a rejection under 35 USC 103 of the other invention.

Applicant is reminded that upon the cancellation of the claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor if at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. 1.48 (b) and by the fee required under 37 C.F.R. 1.17 (h).

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers
Primary Examiner
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